MDS Weekly Conference Call
Wednesday, 22 Nov 2002
10:00 CST, 11:00 EST

Attendees: Hans, Bettie, Martin, Qiwei, Jan, Robin, Mike, Chad, Henry and Kim

1. Follow up on tasks from previous teleconferences

   Tasks:

   a. Ames – final report (validation and concentration –including method development). MDS analytical rough draft sent to PM 20 Nov. Waiting for Lyon version.
   b. Validation for 1, 3-But in Exhalate is complete, starting analysis. 1-OHP and S-PMA next to complete validation. Targeting Dec for analysis
   c. MDS LNK clinic incorrectly ordered urine transfer tubes HDPP instead of HDPE. Transfer tube analysis for absorption is currently ongoing. Possible affect on short and continuation SCoR and long term JLI

2. Update on projects including timelines

   ACCORD E 4 study (26586)

   - Final report revisions being reviewed by MDS
   - Paper version and 3 CDs of final report after revisions completed, mid Dec
   - Database to be transferred on burned CD or DVD by end Dec (Ed Kirstine from MDS will complete the transfer). Yuli will complete biomarker database transfer in mid-Dec
   - Brief data transfer report may be needed

   ACCORD JLI short-term study (28030)

   - All tables finalized and sent 08 Nov, Qiwei to contact Nancy with comments and possible additional calculations. MDS will correct typing errors in summary tables and PM will complete review of data summary results by the end of Dec 2002
   - MDS will conduct additional analysis on topography data, excluding data outliers. Delivery date to be confirmed with Hans
   - 1-3 Butadiene in Exhalate has been analyzed, Nancy to send data this week. MDS will conduct data summary for the additional bio-analysis of NNAL, 1-OHP, S-PMA and 1, 3-But
   - Draft report timelines: 6-8 weeks after comments on tables are received. PM needs by 15 Jan 2003 (date will need to be adjusted)
   - PA for additional analysis, NNAL, 1-OHP, S-PMA and 1, 3-BUT, will be handled as a separate PA (#32), fee under review by PM
   - Analytical scheduling of these analytes needed after validation completed, possibly Dec 2002 (NNAL)/Jan 2003 (all have same priority)

   ACCORD JLI long-term study (28123)

   - Sending ACCORD downloading and subject information bi-monthly

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Group 1 & 2P

mid next wk long-term JLI report

Chips for devices

Timeline for reports

- Several subjects non-compliant with smoking other cigs, to review on case by case basis. Received PM approval to drop #10 for above reason. PM approved subject needing gall bladder surgery to continue on study after the surgery
- For Groups 1 and 2P, the 3-month report, summary statistics, including graphs and tables, was not delivered on 25 Nov due to data management delay in PHX. MDS to confirm new date of report delivery
- After Groups 2P1 and1L1 clinic complete (2P1 completed clinic visit on 02 Nov and 1L1 will complete 3 month clinic visit on 07 Dec), formatting has been agreed upon and sample analysis completed, a full draft report will need to be generated, to PM early Feb 2003
- The final 3 month report will be needed late Feb/early March 2003
- 6-month decision on continuation of the study will need to be made
- Need to decide on Ames testing status
- Analysis plan has been started, needs to be completed by the end of 2002.
- Running short on complete Accord device kits, Bettie to investigate
- Subject 116, on the LNK make up group, tested positive for pregnancy. She was on the ACCORD group. She has been discontinued from the study, per protocol. Letter supplying counseling to quit smoking and available resources, including the PM web page, will be sent to her after PM review
- During the scheduled contacts with this subject, MDS is to inquire if subject stopped smoking
- An error was found regarding the invoicing for past monthly events. MDS will invoice the corrected amounts, per group and month. Hans approved
- Invoicing of subject stipends was discussed. MDS will invoice PM after scheduled subject payments have been made (three times throughout the study for each group). Kim is to review for accuracy prior to sending to Hans

ACCORD JLI Menthol short-term study (AA01190)

- Group 2, started clinic 30 Oct, completed 10 Nov. Samples shipped 12 and 13 Nov. Group 3, started clinic 15 Nov, completed 26 Nov. Samples to be shipped 03 and 04 Dec
- Kim to receive carboxy results, Jan confirmed
- Monitoring of CRF's to be completed by early Jan 2003. MDS enter these for use in the draft report. Need to discuss timelines
- Analysis plan – PM to send comments to MDS on 10 Dec
- Sample analysis, besides Ames, and QA needs to be completed by 08 Jan. MDS re-arranged analytical scheduling for completion dates to be met
- Tables and graphs need to be completed by 15 Jan, with draft report by beginning Feb 2003

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Dispensing info
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General email

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